# SESSION I AHCPR SMOKING CESSATION GUIDELINE: A FUNDAMENTAL REVIEW

# Introduction

Douglas Kamerow

On behalf of the Agency for Health Care Policy and Research (AHCPR), I am delighted to add my welcome to everybody else's at this conference sponsored by the Society on Research on Nicotine and Tobacco (SRNT). I also want to thank the folks at the Robert Wood Johnson Foundation, the people from the National Cancer Institute (NCI), and the Centers for Disease Control (CDC) for their support. One of our goals for the past five years has been to facilitate and foster the development and dissemination of the AHCPR smoking cessation guideline. We now need to move beyond dissemination to adoption, to actually changing clinical practice.

This conference is the beginning of what should be a crusade to move this guideline into practice. We are very proud of the work that the expert panel did in developing this smoking cessation guideline. It was an impressive two-year effort headed by Michael Fiore, MD, MPH, that reviewed the scientific literature, researched the literature, and addressed clinical practice and tobacco use.

The release of the guideline in April has sparked a flurry of interest in cessation activities, which we hope we can now translate into improved health for millions of Americans. Our task is to ensure that the guideline is read and used by the full diversity of healthcare professionals, by providers, and decision makers, who can make a real difference in improving the way tobacco dependence is treated in the United States.

To date, 38 organisations have endorsed the AHCPR guideline, and that is the largest response we have ever had to one of our guidelines (we have issued 20). We are already seeing the adoption of the guideline in various settings, and it is extremely encouraging to see states, health plans, societies-especially societies-and others working to develop materials that could extend the guidelines reach even farther.

For example, the American Psychiatric Association (APA) is putting the finishing touches on a compatible guideline on nicotine dependence, one that is aimed at treating nicotine addiction in populations seen by psychiatrists.2 We have also got representatives from other specialty societies here today, as well as representatives from academia, from health policy, business, public health, insurance, and clinical practice.

We welcome all of you and are looking forward to a productive conference, and more importantly, to continuing to work with you in this vital area. Smoking is the leading cause of death in America.

Although we are gratified at the reception that this guideline has received, we know that it is not enough. It is not enough for it to be well reviewed, it is not enough for it to be disseminated widely-which it has been already, thanks to the Robert Wood Johnson Foundation. We want the AHCPR guideline used. We don't want it sitting on a shelf; we want its principles implemented. We want providers and health plans to have incentives to encourage smoking cessation.

As Dr Tom Kotke of the smoking cessation guideline panel once said, we want you to have to have the skills for smoking cessation and tobacco cessation counselling and to use them, if you want to be a member of the Good Doctor Club, if you want to be a member of the Good Pharmacist Club, or if you want to be a member of the Good Nurses Club. That is what this conference is about: implementation and changed behaviour.

Let me introduce Michael Fiore. Dr Fiore, who was the chair of our guideline panel, worked extraordinarily hard to produce this terrific document. He is a nationally known expert on tobacco. He did yeoman's work for a period of two years as our smoking cessation guideline panel chair. There were times when we wondered if this document would ever come out, but he successfully steered it to completion and to release. He is associate professor in the Department of Medicine, the director of the Center for Tobacco Research and Intervention at the University of Wisconsin, and he is a terrific and unique fellow because he is both an advocate and researcher. In this role, he has written extensively on tobacco and health, and he is co-author of the 25th anniversary Surgeon General's report on tobacco.1 Dr Fiore is here to review the development of the guideline with us, as well as its goals and principal find-

1 US Department of Health and Human Services. Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General, 1989. Rockville, Maryland: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.)

2 Anon. Practice guideline for the treatment of patients with nicotine dependence. Am J Psychiatry 1996;153 Suppl:10.

Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 501, Rockville Maryland 20862, USA D Kamerow

# AHCPR smoking cessation guideline: a fundamental review

Michael C Fiore

This conference brings us together at a crossroads in the way our society views tobacco addiction. I also believe when future historians look back upon the events that led to the elimination of tobacco addiction in our society, they will cite 1996 as a year in which this critical public health goal first appeared attainable. Two events lead me to designate 1996 as such a pivotal time. First, the decision by President Clinton to classify cigarettes as a drug delivery system is both courageous and historic. The head of our government has finally publicly acknowledged the enormous burden to our society resulting from tobacco addiction, and has taken concrete steps to protect another generation of young people from this deadly drug. Many of the individuals in this audience, in large and small ways, contributed to this historic action.

Although this action by President Clinton and the Food and Drug Administration is directed at the primary prevention of tobacco addiction, I would propose that the second critical event in this historic year was the release of the Agency for Health Care Policy and Research (AHCPR) smoking cessation guideline.1 This document, for the first time, clinicians, administrators, and provides smokers alike with a definitive, research-based answer to the question: what actions are necessary to improve the likelihood of successful smoking cessation for people already addicted to tobacco? These two projects-one to prevent children from becoming addicted and the second, to assist those already addicted to tobacco-will (in my view) be defining moments in reaching a goal that finally appears achievable: the elimination of tobacco addiction from our society.

Now I would like to describe to you the procedures we followed in producing the AHCPR smoking cessation guideline. As Dr Kamerow mentioned, the AHCPR convenes expert panels to develop clinical practice guidelines for healthcare practitioners. AHCPR determines the needs for these guidelines based upon several factors including prevalence, related morbidity and mortality, the economic cost of the condition, variations in clinical practice, the availability of methods to improve care, and the availability of data on which to base recommendations.

Because tobacco addiction fulfills all of these criteria, AHCPR convened a panel of experts in 1994 to provide a guideline for clinicians and others addressing tobacco addiction. Although I had the honour of serving as chair of this panel, I need to emphasise that the rec-

ommendations I share with you today are truly the result of a collaborative process involving a national panel of 25 experts and the input of more than 100 peer reviewers. Dr David Wetter at MD Anderson, Houston, Texas, was the project manager, Dr Connie Kohler at the University of Alabama was the project co-manager, and Dr Tim Baker served as senior scientific adviser on the project and ensured that the guideline reflected the highest quality of scientific investigation. [A reprint of the April 1996 consensus statement originally published by the panel in the Journal of the American Medical Association follows this address.]

What were the goals of this guideline process? At the start, the panel established two: first, to determine in a succinct, exact, and clear manner which clinical interventions promote smoking cessation and which do not; and second, to write a guideline that would move both the clinical and healthcare delivery communities to view smoking cessation intervention not as an afterthought, but as a required part of every clinical encounter.

To whom did we direct these guidelines? The panel recognised that, unlike many clinical protocols, a smoking cessation guideline needed to address an audience beyond just the practicing physician. For this reason, and recognising the unique desire to institutionalise the AHCPR guideline, the panel identified three key audiences.

The first included primary care clinicians for whom smoking cessation is just one of a number of activities in which they are engaged. The panel was specific throughout this guideline in using the word clinician rather than physician, recognising that, to be maximally effective in this area, the whole healthcare delivery community—from medical assistants to nurses to health educators to dentists to pharmacists—has to assume responsibility.

The second audience included smoking cessation experts who provide intense interventions. Here, the panel's aim was to define which of these intensive interventions are most effective.

Finally, in an innovative move, the panel identified healthcare administrators, purchasers, and insurers as the third targeted audience. The panel recognised that these individuals frequently determine what healthcare is delivered in America. Panel members understood that, unless we had the managed care organisations and other administrators on

Center for Tobacco Research and Intervention, University of Wisconsin Medical School, 7278 MSC, 1300 University Avenue, Madison, Wisconsin 53706-1532, USA M C Fiore board, we would not be able to implement a smoking cessation guideline broadly.

What process produced this guideline over the two years? The agency identified a panel of experts, who were supported by staff at Wisconsin and at the University of Alabama. First, the panel isolated the years between 1975 and 1994 and attempted to do a complete review of all the literature published during that time. A priori criteria were established to identify what would serve as evidence-based data for recommendations.

The process yielded more than 3000 articles from which 300 fulfilled the criteria. We produced evidence tables based on these 300 articles which then served as the basis for more than 50 meta-analyses. The panel identified randomised control trials as the strongest level of evidence for evaluating treatment efficacy and for making recommendations. In addition, we had to have at least five months of follow up from the quit date before we would use such data.<sup>2</sup>

The meta-analyses were conducted under the direction of Dr Vic Hasselblad at Duke University [Durham, North Carolina]. Combined with panel expert opinion, the meta-analyses served as the basis of our recommendations. A preliminary guideline was written by the panel and staff and distributed to 100 peer reviewers across the nation. These reviewers provided feedback that allowed us to product the final guideline, released in April 1996.

Since the AHCPR guideline was released in April of this year, the agency has received more than 50 000 requests for the full guideline and more than 400 000 requests for the associated products: the quick reference guide for clinicians, for smoking-cessation specialists, and a guide for smokers who want to quit. And final product is still in the works—a quick reference guide for healthcare administrators, insurers, and purchasers.

At the start of its deliberations, the panel identified a number of questions that were not definitively answered in the literature, all regarding various aspects of smoking cessation. I would like to share with you now the questions we asked, and our answers to some of those questions.

The first question involved the issue of the efficacy of screening for tobacco use. Dr Orleans shared with us earlier that, in repeated national surveys, large numbers of Americans report that they have not been asked about their smoking status or provided with specific advice on quitting. So, we considered a simple question: if we universally identify the tobaccouse status of patients as they walk through the door, what will be the impact on the rate at which clinicians intervene with patients identified as smokers?

Specifically, our meta-analysis considered the rates of clinician intervention if a screening system was in place, and compared them with those clinical settings where no screening system was in place. What is the impact of such a screening system? This meta-analysis included nine studies and allowed us to deter-

mine an odds ratio. Simply having a screening system in place resulted in an odds ratio of 3.1 for clinician intervention, compared with settings that altogether lacked a system.

This process clearly identified the critical importance of universal identification of tobacco use status. As a result, the panel—in one of its key recommendations—urged that such a system be implemented in every clinical setting. Each time patients walk through clinic doors, regardless of what brings them to that clinic, their tobacco-use status should be established and documented, just as their vital signs are.

The second question addressed by the panel was the importance of simple advice to quit. This responded to a reservation voiced frequently by clinicians: "Why spend time urging my patients to quit when it doesn't seem to have any impact?" We looked at the impact of very brief advice by a clinician to quit, conducting a meta-analysis involving seven studies. The meta-analysis yielded a odds ratio of 1.3. In terms of cessation, it increased the quit rates from about 8 to 10%.

Some might ask why would we urge an intervention that resulted in an increase in cessation efficacy of only 2%. In fact, the panel estimated that this action itself could increase by 1 million *per annum* the number of smokers that successfully quit. Therefore, the panel clearly and strongly urged that physicians, as well as all other clinicians, advise their patients to quit smoking in a clear, strong, unequivocal manner.

Another important question addressed by the panel concerned the need for specialised assessment instruments. This concern resulted from the demonstrated brevity of clinicians' interaction with patients. A recent study suggested that the average physician spends nine minutes with a patient at each encounter. Given these time constraints, many clinicians are reluctant to administer specialised assessment instruments.

The panel found that the success rates of quitting will vary according to the factors that bring patients into the healthcare setting. Highly dependent smokers may have more severe withdrawal symptoms, for example, whereas people with psychiatric comorbidity have lower cessation rates overall. Many factors are associated with lower cessation rates. However, the panel determined that there is no requirement that clinicians administer specialised assessments. Moreover, the panel stated that, for primary care clinicians who are administering brief cessation treatments, such assessments are not necessary.

What of the format of the intervention? Specifically, do self-help materials when used alone result in higher quit rates? Or is it necessary to provide in-person individual or group counselling? A meta-analysis conducted by the panel found that self-help treatments alone did not statistically increase success rates. Although the odds ratio was 1.2, the 95% confidence intervals included 1.0, so the panel concluded that self-help materials alone are not effective treatment. Yet both group and individual

counselling were effective in promoting smoking cessation. The panel then chose to examine what specific types of self-help materials may be helpful in promoting cessation. In a surprising finding, the materials most used—pamphlets, booklets, and manuals—by themselves had virtually no impact on cessation rates. They had an odds ratio of 1.0.

In fact, the only type of self-help material that was particularly efficacious was telephone helplines and hotlines. This modality is currently being tested in an innovative way in research conducted by Dr Vic Strecher and others. Their use of personalised telephone lines holds enormous promise although there were not enough data on this technique for the panel to evaluate. The panel did not, however, recommend that we throw away all self-help booklets. In fact, when used in combination with a brief intervention by a clinician, these may have an important impact on a patients' efforts to successfully quit.

Another question examined by the panel was: Can every clinician provide effective smoking cessation treatments? The panel looked at a wide variety of healthcare providers and found that every type of clinician can improve a patient's chance of successful smoking cessation. This finding led the panel to urge that the whole healthcare team be involved in delivering smoking cessation treatments.

How intense must a cessation intervention be to promote quitting? Through a meta-analysis, the panel found that interventions as brief as three minutes or less resulted at higher rates of smoking cessation. This meta-analysis yielded another important finding: there was a clear and powerful dose-response relationship. The more time a clinician spent in providing counselling, the higher the rates of smoking cessation.

Next, the panel turned to the question of what components a brief counselling intervention should include. We all know that there is an endless variety of cessation programmes and counselling interventions. While the panel examined most of these content types, the good news in terms of translating the message to clinicians is that only two components of counselling were found to be particularly efficacious: social support provided by a clinician and problem solving/skill training.

To assist clinicians, the AHCPR guideline provides very detailed information, the nuts and bolts of these two counselling components. Some of the key elements of problem solving/skills training include recognising dangerous situations, developing coping skills, and providing some of the basic information on quitting. Some of the key elements of social support including simply encouraging the patient in that quit attempt, communicating care and concern, encouraging the patient to talk about the quitting process, and providing some basic information about smoking and successful quitting.

Another issue addressed by the AHCPR panel was how long treatment should last. In this instance, the panel again found a clear

dose-response relationship; the longer the duration of treatment, the higher the rates of smoking cessation success. Additionally, the greater the number of sessions with a patient, the higher the rate of smoking cessation success.

Next, I want to discuss pharmacological interventions to promote cessation, because we are in a changing environment regarding this quitting option. The panel examined all of the available pharmacotherapies and found that there was powerful evidence for only two medications to promote smoking cessation: nicotine gum and transdermal nicotine. Both the nicotine patch and gum nearly doubled the rates at which patients successfully quit, regardless of the degree of adjuvant counselling that accompanied them. Even when used with minimal or no counselling, such nicotine (NRT) statistically replacement therapy increased the rates at which people successfully quit. As a result, the panel recommended that either the patch or the gum be used by every patient in every quit attempt in the absence of major medical contraindications.

By September 1996, these two NRT products were available over the counter. Regarding this change, the AHCPR panel sends specific messages to clinicians: even in an over-the-counter context, clinicians need to address tobacco addiction, to provide counselling, and to urge their patients to use these products (either to buy them over the counter or obtain prescriptions) to ensure that patients have the greatest likelihood of quitting smoking.

Other medications have also been tried and proposed for smoking cessation. Possibly the most notable of these is clonidine. The panel found that there was no evidence to support the use of clonidine as an adjuvant for smoking cessation. Anxiolytic agents also were not shown to be efficacious, and the few trials available at the time with antidepressant agents were not conclusive. I believe one potential cessation treatment over the next year or two may involve new antidepressant agents. Bupropion, for example, is being tested as a smoking cessation aid and holds promise. There were not sufficient data at the time the AHCPR guideline was released to recommend any agents beyond the nicotine gum and patch.

There were key institutional changes that the panel identified as central to ensure the universal identification and intervention with patients who smoke. Although these recommendations were based on a modest amount of data, the panel strongly recommended that clinicians be encouraged in and reimbursed for providing smoking cessation services. The panel felt that in the absence of such encouragement, it would be impossible to implement the guideline universally. The panel also recommended strongly that smoking cessation services shown to be effective in this guideline-both counselling and pharmacotherapy—need to be included as covered services in insurance policies and managed care contracts.

Major findings and recommendations of the AHCPR smoking cessation clinical practice guideline

- 1 Effective smoking cessation treatments are available, and every patient who smokes should be offered one or more of these treatments.
- 2 It is essential that clinicians determine and document the tobacco-use status of every patient treated in a healthcare setting.
- 3 Brief cessation treatments are effective, and at least a minimal intervention should be provided to every patient who uses tobacco.
- 4 A dose-response relation exists between the intensity and duration of a treatment and its effectiveness. In general, the more intense the treatment, the more effective it is in producing long-term abstinence from tobacco.
- 5 Three treatment elements, in particular, are effective, and one or more of these elements should be included in smoking cessation treatment.
  - Nicotine replacement therapy (nicotine patches or gum) Social support (clinician-provided encouragement and
  - assistance) Skills training/problem solving (techniques on achieving
  - and maintaining abstinence).
- 6 Effective reduction of tobacco use requires that healthcare systems make institutional changes that result in systematic identification of, and intervention with, all tobacco users at

Why is it that in 1996, virtually every insurance plan in America will pay for the outcome of tobacco use, whether it be heart attacks, lung cancer, or strokes, and fewer than 50% of such plans pay for smoking cessation services? This has to change.

Now, I would like to turn to the six key findings of the guideline. First, the panel concluded that effective smoking cessation treatments are available and that every patient present in a healthcare setting should be offered such a treatment.

Second, the guideline panel urges that every patient who walks through a clinic door needs to have his or her tobacco-use status determined and documented, and that institutional systems be put into place to ensure that happens. To be effective, this must be not only a requirement of the clinician, but a part of the regular delivery of healthcare for all patients.

Third, the panel found that brief cessation interventions, as short as three minutes, are effective and every smoker should at least get a brief intervention.

Fourth, there was a clear dose-response relationship; more intense interventions result in higher rates of quitting.

Fifth, the panel identified three treatment elements that are particularly effective and should be part of every patient's cessation intervention: nicotine replacement therapy; clinician-provided social support; and skills The AHCPR solving. training/problem guideline provides clinicians with the nuts and bolts of how to use these three treatment elements.

Lastly, the effective reduction of tobacco use requires that healthcare systems make institutional changes that result in the systematic identification and intervention with patients that smoke (table). It is not enough just to push the clinician. Universal smoking cessation treatment will not result from continuing medical education (CME) programmes alone. We need to institutionalise the AHCPR guideline to make it work.

A key issue that healthcare administrators and managed-care organisations need to address further is the whole issue of cost effectiveness. As a separate activity, AHCPR commissioned a research group to look at the cost effectiveness of implementing it guideline. Those findings are still in draft form; we hope to release them in early 1997. However, I want to share with you two preliminary findings of that effort.

First, the implementation of this guideline results in the most cost effective preventive intervention that is available to clinicians and healthcare systems today. Overall, our using guideline recommendations costs US\$2000-3000 per year of life saved, which is an extraordinarily low rate of cost for a preventive intervention. To put that in context, screening mammography costs approximately \$50 000 per year of life saved. The second finding of importance is that more intense interventions, because of their higher cessation rates are in fact more cost effective than brief interventions. This could be an important finding to support and encourage intensive treatment that are frequently unavailable to American smokers today.

I want to end with some of the implications of this guideline. The AHCPR guideline panel recognised that there is no one "cessation cookbook" that is going to be perfect for every patient that uses tobacco. We need to identify and address some specific populations and issues that may require individualised treatment. The guideline has sections on each of these populations and issues. Clearly, pregnant women are a critical group that need to be addressed; there is no other population for which smoking cessation interventions could have the same impact and rapid rate of return from the point of view of health and economics.

The panel recognises there is virtually no data available on how to how to help adolescent smokers to quit. Moreover, there is little data on what might help racial and ethnic minority groups, some of which have higher rates of smoking cessation in our society. The panel also recognised the unique opportunity to influence hospitalised patients who smoke, especially now that every hospital in America is The panel urges that all smoke-free. hospitalised patient be asked about their smoking status and that a smoking cessation intervention be offered to every smoker admitted to a hospital. Weight gain after quitting is another critical issue, particularly for women.

As Dr Kamerow mentioned, the American Psychiatric Association is releasing its guideline on smoking cessation,3 specifically psychiatric dealing with patients with comorbidity. Finally, the panel considered smokeless tobacco use. Unfortunately, this was another area where there were little data specifically on cessation.

view, the AHCPR guideline In my challenges the healthcare delivery community to change the culture in which clinicians provide healthcare. I suggest that we no longer view smoking cessation intervention as an optional afterthought, but rather as part of an appropriate standard of care. As a clinician, I believe I should be judged as not providing an appropriate standard of care if I do not ask every patient if he or she smokes and further, intervene with each of my patients identified as a smoker.

Some of the implications of changing this culture is the need to institutionalise the identification and documentation of tobacco use status. As I mentioned earlier, I believe this is not just something that we relegate to clinicians, but rather it must be a shared responsibility of both clinicians and the healthcare delivery community. This guideline is the first to challenge managed-care organisations to be in the forefront.

Additionally, the AHCPR guideline urges all of us to change our attitude towards tobacco use, to view it not as an acute event requiring a single clinical encounter, but rather as a chronic disease. As with other chronic diseases, we need to recognise that tobacco addiction has periods of relapse and remission. As clinicians in healthcare delivery systems, we need to stand by each patient who smokes for as long as it takes to move that individual to a status of long-term remission from tobacco dependence.

When I speak to clinicians, they frequently point out how frustrating it is to deal with smoking cessation success rates of 5 or 10%, according to the guideline findings. But I urge clinicians to treat tobacco addiction as a

chronic disease. What other chronic diseasewhether it be hypertension, hyperlipidaemia, or diabetes—do we deal with as clinicians that can be ameliorated by 3-5-minute counselling sessions that result in 5-10% of our patients achieving long-term remission? There is not a single intervention out there with this potential impact. We all need to involve both clinicians and systems to ensure this intervention happens.

From the very beginning, the panel intended to determine which interventions promote smoking cessation and which do not. The panel answered this question unequivocally. No longer will clinicians or insurers be able to say that they do not know what helps their patients, and therefore choose to do nothing at all. The AHCPR guideline based its response upon the science. It concluded that cessation treatments should be implemented in every setting. Now we need to ensure that this guideline is universally institutionalised. That goal clearly remains unattained. However, this conference has enormous potential to move us closer to it.

- Fiore MC, Bailey WC, Cohen SJ, et al. Smoking cessation. Clinical Practice Guideline No 18. Rockville, Maryland: US Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, April 1996. (AHCPR Publication No 96-0692.)
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- Anon. Practice guidelines for the treatment of patients with nicotine dependence. Am J Psychiatry 1996;153Suppl:10.

# Consensus statement: Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline

Smoking Cessation Clinical Practice Guideline Panel and Staff

## **Abstract**

Objective-To summarize the Smoking Cessation Clinical Practice Guideline that provides recommendations for three groups of professionals: primary care clinicians, smoking cessation specialists, and health care administrators, insurers, and purchasers.

Participants-An independent panel of scientists, clinicians, consumers, and methodologists selected by the US Agency for Health Care Policy and Research.

Evidence—English-language, reviewed literature published between and 1994 that addresses assessment and treatment of tobacco dependence, nicotine addiction, and clinical practice.

Consensus process-Four panel meetings were held over two years to evaluate meta-

analytic and other results, to synthesize the results, and to develop recommendations. The Guideline was repeatedly reviewed and revised.

Conclusions—The panel recommendations address three audiences. Major recommendations for primary care clinicians are to use officewide systems to identify smokers, treat every smoker with a cessation or motivational intervention, offer nicotine replacement except in special circumstances, and schedule follow-up contact to occur after cessation. Major recommendations to smoking cessation specialists are to use multiple individual or group counseling sessions lasting at least 20 minutes each with sessions spanning multiple weeks, offer nicotine replacement, and provide problem-solving and social support counseling. Major recommendations

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A complete list of the members of the Smoking Cessation Clinical Practice Guideline Panel and Staff appears at the end of this article.

Correspondence to: Dr Michael C Fiore, Center for Tobacco Research and Intervention, University of Wisconsin Medical School, 1300 University Ave, Madison, Wisconsin 53706,

for health care administrators, insurers, and purchasers are that tobacco-user identification systems be used in all clinics and that smoking cessation treatment be supported through staff education and training, dedicated staff, changes in hospital policies, and the provision of reimbursement for tobacco-dependence treatment.

Tobacco addiction in the United States presents a rare confluence of circumstances that mandates clinical intervention: (1) It is a highly significant health threat, (2) there is a disinclination among clinicians to intervene consistently, and (3) effective preventive interventions are now available. Smoking cessation treatment is preventive because if it is provided in a timely and effective manner, it greatly reduces the smoker's risk of suffering from smoking-related disease. Indeed, it is difficult to identify a condition in the United States that presents such a mix of lethality, prevalence, and neglect, and for which effective interventions are so readily available.

The US Agency for Health Care Policy and Research (AHCPR) convenes expert panels to develop clinical guidelines for health care practitioners. AHCPR determines the need for guidelines for a given condition based on several factors including prevalence, related morbidity and mortality, the economic burden imposed by the condition, variation in clinical practice related to the condition, the availability of methods for improvement of care, and the availability of data on which to base recommendations for care. Because tobacco addiction in the United States fulfills all of these requirements, AHCPR convened a panel of experts in 1994 to provide guidelines to clinicians on the treatment of tobacco addiction.

This article summarizes the key recommendations of the Smoking Cessation Clinical Practice Guideline (the Guideline).2 The article is intended to serve as a state-of-the-art primer for clinic-based tobacco intervention rather than as a technical document. Readers interested in more details regarding the literature review, data analytic methods, and the consensus process may refer to the Guideline. Both the full Guideline and the present article are targeted at three principal audiences: (1) the broad range of primary care clinicians for whom smoking cessation is just one of their many clinical activities, (2) smoking cessation specialists for whom smoking cessation treatment is a major professional activity, and (3) health care administrators, insurers, and purchasers. Key recommendations and findings of importance for each of these groups are presented in turn and highlighted in a series of tables. These audience-specific recommendations are followed by clinical information and recommendations regarding cessation-relevant topics (e.g., weight gain, smokeless tobacco) of importance to members of all three audiences. The Guideline offers a simple and flexible set of strategies designed to ensure that all patients who use tobacco are offered motivational

interventions and effective treatments to overcome this powerful addiction.

# Overview of guideline development procedures

The Guideline is intended to identify empirically based and validated assessments and treatments for tobacco dependence. The principal steps in guideline development were the following:

- 1. The Smoking Cessation Panel formulated clinically significant questions to be addressed in literature reviews and analyses.
- 2. Approximately 3000 research articles and abstracts were reviewed to identify research reports appropriate for evaluation. In addition to the appropriateness of the content and topic, other inclusion criteria were that the article concerned a randomized controlled trial, had a follow-up end point at least 5 months after the quit date, and was published in English in a peer-reviewed journal between 1975 and 1994.
- Three independent raters coded features of all screened and accepted research reports.
- 4. Whenever possible, the research reports selected for an analytic question were analyzed via random effects logistic regression meta-analysis.<sup>3</sup> Analyses were often repeated with restricted data sets. For instance, the analysis might be restricted to studies with biochemical verification of abstinence, or studies in which subjects took no active steps to seek treatment ("all comers" studies). In general, meta-analytic findings were consistent across these restricted analyses. All follow-up data used in analyses were collected at least 5 months following smoking cessation.
- 5. The results of all meta-analyses, and any other relevant data (e.g., preexisting meta-analyses), were made available to the Guideline panel, who examined the findings and, when warranted, made requests for additional data and analyses.
- 6. Once the Guideline panel believed that it possessed sufficient data, it generated evidence statements that characterized findings and recommendations that were derived from the findings.
- 7. Recommendations and evidence statements were assigned an A, B, or C level "strength of evidence" rating according to the following criteria:
  - A. Consistent evidence from multiple, welldesigned randomized clinical trials (or trials that departed only minimally from randomization) in the populations for which the recommendation is made.
  - B. The same type of evidence as in A, but involving a smaller number of studies and/or a less consistent pattern of findings and/or in need of panel opinion for generalization on a variable thought to affect response to treatments.
  - C. Evidence from clinical experience described in the literature and/or derived from the consensus of panel members.

8. The entire Smoking Cessation Clinical Practice Guideline was then reviewed by professionals with expertise in tobacco addiction, smoking cessation clinical care, and related topics. The Guideline was modified based on this feedback.

## Guideline recommendations

PRIMARY CARE CLINICIANS

Primary care clinicians are uniquely poised to assist patients who smoke, as they have extraordinary access to this population. At least 70% of smokers see a physician each year, and more than 50% see a dentist.45 Moreover, 70% of smokers report that they want to quit and have made at least one self-described serious attempt to quit.6 Finally, smokers cite a physician's advice to quit as an important motivator for attempting to stop.7-9

Unfortunately, clinicians are not capitalizing fully on this unique opportunity. Only about half of current smokers report having ever been asked about their smoking status or urged to quit.10-12 Fewer still have received specific advice on how to quit smoking successfully.

Why don't clinicians consistently address tobacco use among their patients? Some clinicians' reluctance to intervene may be attributed, in part, to time constraints, a perceived lack of skills to be effective in this role, frustration due to low success rates, or even a belief that smoking cessation is not an important professional responsibility.13 Several changes have been proposed to increase clinicians' intervention with smokers:

(1) Health care delivery practices must change so that smoking cessation interventions are institutionalized; (2) clinicians and their patients must be reimbursed by insurers for smoking cessation counseling and pharmacotherapy; (3) clinicians must adjust their goals so that motivational interventions are offered to smokers who are not yet committed to quitting14; and (4) standards of health care delivery must reflect the health care system's obligation to intervene in a timely and appropriate manner with patients smoke.15 16

In this section, specific recommendations relevant to primary care clinicians (e.g., physicians, nurses, dentists, physician assistants, respiratory therapists) are presented. These recommendations are designed to be brief and to be consistent with those produced by the National Cancer Institute in How to Help Your Patients Stop Smoking17 and by the American Medical Association Guidelines for the Diagnosis and Treatment of Nicotine Dependence: How to Help Your Patients Stop Smoking,18 as well as others. The goals of these recommendations are clear-to change clinical culture and practice patterns to ensure that every patient who smokes is offered treatment. The recommendations revolve around a central theme: It is essential to provide effective cessation intervention for all tobacco users at each clinical visit.

Several observations are relevant to this theme. First, institutional changes in clinical practice are necessary to ensure that all

patients who smoke are identified. Second, although more intensive interventions produce greater success, the compelling time limitations on primary care clinicians in the United States today (the median visit is approximately 12 minutes long19) demand brief interventions. Third, because many smokers are reluctant to enter intensive cessation programs,20 they must receive treatment every time they visit a primary care clinician.

The AHCPR Guideline recommendations for primary care clinicians (Table 1) emphasize the importance of systematically identifying all smokers (step 1) (Figure), strongly advising all smokers to quit (step 2), and determining patients' willingness to make a quit attempt (step 3). Those patients not willing to commit themselves to quitting should receive a motivational intervention to promote subsequent quit attempts. When patients are willing to make a quit attempt, primary care clinicians should assist the patients in their efforts (step 4) by helping the patient set a quit date, preparing the patient for the quit date, offering nicotine replacement therapy, providing self-help materials, and providing key advice including problem solving (also referred to as skill training) (Table 2) and social support (Table 3). If the patient prefers a more intensive treatment, or if the clinician believes more intensive treatment is appropriate, the patient should also be referred to an intensive program (see below). All patients attempting to quit should have follow-up contact scheduled (step 5).

Finally, the panel identified nicotine replacement therapy (nicotine patches and nicotine gum) as the only pharmacotherapy currently shown to be effective as an aid to smoking cessation. The panel recommends that, unless there is a clear medical contraindication, all patients planning a quit attempt should be offered nicotine replacement therapy. While both the nicotine patch and nicotine gum were found to be efficacious, the panel felt the patch is preferable for routine clinical use because of greater compliance and ease of use. Specific instructions for clinicians on the use of the nicotine patch and nicotine gum are provided in Tables 4, 5, and 6.

### Tobacco cessation specialists and programs

Smoking cessation specialists are not defined by their professional affiliation or by the field in which they were trained. Rather, the specialist views smoking cessation as a critical professional role, possesses skills relevant to cessation activities, and is often affiliated with programs offering intensive cessation interventions or services.

Specialists are a vital resource in smoking cessation efforts. As major contributors to cessation research, specialists exert a cumulative effect greater than their numbers. Also, specialists play an important role in service delivery, especially through the provision of intensive cessation interventions. Intensive interventions are not typically offered by nonspecialists, and there is substantial evidence that such intensive programs produce

Table 1 Actions and strategies for the primary care clinician

Strategies for implementation

## Step 1. Ask-systematically identify all tobacco users at every visit

Implement an officewide system that ensures that for every patient at every clinic visit, tobacco-use status is queried and documented.\*

Expand the vital signs to include tobacco use.

Data should be collected by the health care team.

The action should be implemented using preprinted progress note paper that includes the expanded vital signs, a vital signs stamp, or, for computerized records, an item assessing tobacco-use status (see Figure). Alternatives to the vital signs stamp are to place tobacco-use status stickers on all patients' charts or to indicate smoking status using computerized reminder systems.

## Step 2. Advise-strongly urge all smokers to quit

In a clear, strong, and personalized manner, urge every smoker to quit.

Advice should be

Clear: "I think it is important for you to quit smoking now, and I will help you." "Cutting down while you are ill is not enough.

Strong: "As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your current and future health."

Personalized: Tie smoking to current health or illness and/or the social and economic costs of tobacco use, motivational level/readiness to quit, and the impact of smoking on children and others in the household. Encourage clinic staff to reinforce the cessation message and support the patient's quit attempt.

#### Step 3. Identify smokers willing to make a quit attempt

Ask every smoker if he or she is willing to make a quit attempt at this time.

If the patient is willing to make a quit attempt at this time, provide assistance (see step 4).

If the patient prefers a more intensive treatment or the clinician believes more intensive treatment is appropriate, refer the patient to interventions administered by a smoking cessation specialist and follow up with him or her regarding quitting (see step 5).

If the patient clearly states he or she is not willing to make a quit attempt at this time, provide a motivational intervention (Table 10).

## Step 4. Assist-aid the patient in quitting

A. Help the patient with a quit plan.

Set a quit date: Ideally, the quit date should be within two weeks, taking patient preference into account.

Help the patient prepare for quitting: The patient must: Inform family, friends, and coworkers of quitting and request understanding and support.

Prepare the environment by removing cigarettes from it. Prior to quitting, the patient should avoid smoking in places where he or she spends a lot of time (e.g., home, car).

B. Encourage nicotine replacement therapy except in special circumstances

C. Give key advice on successful quitting.

Review previous quit attempts. What helped? What led to relapse?

Anticipate challenges to the planned quit attempt, particularly during the critical first few weeks. Encourage the use of the nicotine patch or nicotine gum therapy for smoking cessation (see Tables 4 and 5

for specific instructions and precautions).

Abstinence: Total abstinence is essential. "Not even a single puff after the quit date."

Alcohol: Drinking alcohol is highly associated with relapse. Those who stop smoking should review their alcohol use and consider limiting or abstaining from alcohol use during the quit process.

Other smokers in the household: The presence of other smokers in the household, particularly a spouse, is associated with lower success rates. Patients should consider quitting with their significant others and/or developing specific plans to maintain abstinence in a household where others still smoke

Source: Federal agencies, including the National Cancer Institute and the Agency for Health Care Policy and Research; nonprofit agencies (American Cancer Society, American Lung Association, American Heart Association); or local or state health departments.

Selection concerns: The material must be culturally, racially, educationally, and age appropriate for the patient. Location: Readily available in every clinic office.

## D. Provide supplementary materials.

Step 5. Arrange-schedule follow-up contact Schedule follow-up contact, either in person or via telephone.

Timing: Follow-up contact should occur soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated. Actions during follow-up: Congratulate success. If smoking occurred, review the circumstances and elicit recommitment to total abstinence. Remind the patient that a lapse can be used as a learning experience and is not a sign of failure. Identify the problems already encountered and anticipate challenges in the immediate future. Assess nicotine replacement therapy use and problems. Consider referral to a more intense or specialized program.

higher success rates than do less intensive interventions (as is indicated by several findings of the present Guideline). Additionally, the cessation interventions offered by specialists are important because many nonspecialists do not consistently and reliably intervene with smokers.

While the specialist definitely makes a substantial contribution to smoking cessation efforts, there are constraints that limit the impact of the specialist's service. For instance, only a minority of smokers participate in the intensive programs typically offered by specialists.21 Such considerations suggest that the specialist should contribute to smoking cessation efforts through other activities in addition to service delivery per se. Some activities in which specialists may become increasingly involved in the future include the following:

Serving as a resource to nonspecialists who offer smoking cessation services as part of general health care delivery. This might include training nonspecialists in counseling strategies, providing consultation

	٧	ital signs	
Blood pressure	e:		
Pulse:		Weight:	
Temperature:_			
Respiratory ra	te:		
Tobacco use:	Current	Former (circle one)	Never

A vital signs stamp or sticker that includes an indication of smoking status should be placed on patients' charts at each clinic visit.

difficult cases, and providing specialized assessment services.

- Developing and evaluating changes in office or clinic procedures that increase the rates at which smokers are identified and treated.
- Conducting evaluation research to determine the effectiveness of ongoing smoking cessation activities in relevant institutional settings.
- Developing and evaluating innovative treatment strategies that increase the costeffective delivery of smoking cessation services. For example, treatment-matching, 22 23

<sup>\*</sup>Repeated assessment is not necessary in the case of the adult who has never smoked or not smoked for many years, and for whom this information is clearly documented in the medical record.

Table 2 Common elements of problem-solving/skill-training smoking cessation treatments

Problem-solving treatment components	
	Examples
Component  Recognition of dangerous situations  Identification of events, internal states, or activities that are thought to increase the risk of smoking or relapse	Using alcohol  Using alcohol  Using alcohol
Development of coping skills  Identification and practice of coping or problem-solving skills, which typically are intended to cope with dangerous situations	Learning to anticipate and avoid tangerous to a continuous transparent to the continuous trategies that will reduce negative moods. Accomplishing lifestyle changes that will reduce stress, improve quality of life, or produce pleasure. Learning cognitive and behavioral activities that distract attention from smoking the complete transparent
Provision of basic information  The provision of basic information about smoking and successful quitting	urges The nature and time course of withdrawal The addictive nature of smoking The fact that any smoking (even a single puff) increases the likelihood of full relapse

stepped-care approaches,<sup>24-26</sup> and smoking cessation interventions for patients with psychiatric comorbidity<sup>27</sup> represent three such innovative approaches.

Given that the specialist may assume diverse roles regarding smoking cessation—treatment, assessment, training of nonspecialists, and program development and evaluation—it is apparent that virtually all of the information in the Guideline might be important to the specialist. However, highlighted in Table 7 are Guideline findings that seem particularly relevant to the specialist's implementation of intensive cessation programs.

The findings in Table 7 lead to the recommendations regarding intensive smoking cessation programs presented in Table 8. Of course, implementation of these recommendations depends on factors such as resource availability and time constraints.

# Health care administrators, insurers, and purchasers

Although clinical practice guidelines have traditionally focused on the role of the individual clinician, promoting smoking cessation in the United States requires a broader approach involving health care delivery administrators, insurers, and purchasers. Why broaden the scope of this document beyond the individual clinician? Smoking cessation

efforts directed solely at the individual clinician have yielded disappointing results. National data suggest that in a given visit with a clinician, most smokers are not advised and assisted with cessation.<sup>12</sup>

Factors that contribute to this problem include the failure to include smoking assessment and cessation in the performance expectations of clinicians and the failure to provide clinicians with an environment that supports systematic intervention with smokers. Without supportive systems, policies, and environmental prompts, the individual clinician cannot be counted on to assess and treat tobacco use reliably. In addition, an increasing number of Americans are receiving their health care in managed care settings. The structure of managed care environments provides new opportunities to identify and treat patients who smoke. These factors indicate that responsibility for smoking cessation treatment must be redistributed; just as every clinician has a professional responsibility to assess and treat tobacco users, health care administrators, insurers, and purchasers have a responsibility to craft policies, provide resources, and display leadership in fostering smoking cessation efforts.

Smoking cessation treatments (both pharmacotherapy and counseling) are not consistently provided as paid services for subscribers of health insurance packages<sup>28</sup>; one

Table 3 Common elements of supportive smoking treatments

	Examples
Encouragement of the patient in the quit attempt  Communication of caring and concern	Note that effective cessation treatments are now available. Note that half of all people who have ever smoked have now quit. Communicate belief in the patient's ability to quit. Ask how the patient feels about quitting.
Directly express concern and a willingness to help.  Directly express concern and a willingness to help.  Be open to the patient's expression of fears of quitting, difficulties experienced, and ambivalent feelings.  Encouragement of the patient to talk about the quitting process	Ask about Reasons that the patient wants to quit. Difficulties encountered while quitting. Success the patient has achieved.
Provision of basic information about smoking and successful quitting	Concerns or worries about quitting.  Inform the patient about The nature and time course of withdrawal. The addictive nature of smoking. The fact that any smoking (even a single puff) increases the likelihood of full relapse.

Table 4 Suggestions for the clinical use of the nicotine patch

Parameter of clinical use	Suggestion The ricoting patch should				
Patient selection Precautions  Dosage*	Appropriate as a primary pharmacotherapy for smoking cessation  Appropriate as a primary pharmacotherapy for smoking cessation  Pregnancy: Pregnant smokers should first be encouraged to attempt cessation, with its potential benefits, outweighs the risk of nicotine  be used during pregnancy only if the increased likelihood of smoking cessation, with its potential benefits, outweighs the risk of nicotine  be used during pregnancy only if the increased likelihood of smoking cessation, with its potential benefits, outweighs the risk of nicotine  be used during pregnancy only if the increased likelihood of smoking cessation, with its potential benefits, outweighs the risk of nicotine  peach and potential concomitant smoking. Similar factors should be considered in lactating women.  Cardiovascular diseases: While not an independent risk factor for acute myocardial events, the nicotine patch should be used only after  Cardiovascular diseases: While not an independent risk factor for acute myocardial events, the nicotine patch should be used only after  Cardiovascular diseases: While not an independent risk factor for acute myocardial events, the nicotine patch should be used only after  Cardiovascular diseases: While not an independent risk factor for acute myocardial events, the nicotine patch should be used only after  Cardiovascular diseases: While not an independent risk factor for acute myocardial events, the nicotine patch should be used only after  Skin reactions: Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and  Skin reactions: Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and  Skin reactions: Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and  Skin reactions: Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and  Skin reactions: (5%) or triamcinolone cre				
	Brand	Duration (weeks)	Dose (mg/h)		
	Nicoderm and Habitrol	4 then 2 then 2	21/24 14/24 7/24 22/24		
	Prostep	4 then 4	11/24 15/16		
	Nicotrol	4 then 2	10/16 5/16		
		then 2			

<sup>\*</sup>These dosage recommendations are based on a review of the published research literature and do not necessarily conform to package insert information.

survey demonstrated that only 11% of health plans provided coverage for the treatment of nicotine addiction.<sup>29</sup> This lack of coverage is particularly surprising given that studies have shown that physician counseling against smoking is at least as cost-effective as several common preventive medical practices, including the treatment of mild or moderate hypertension and an elevated cholesterol level.<sup>30</sup> These and other findings have recently led the Centers for Disease Control and Prevention to identify universal reimbursement for the treatment of nicotine addiction as an important national public health goal.<sup>31</sup>

Health care delivery administrators, insurers, and purchasers can promote cessation of tobacco use through a systems approach. Purchasers (usually corporations, companies, or other consortia that purchase health care benefits for a group of individuals) should consider making tobacco-use assessment, counseling, and treatment a contractual obligation of the health care insurers and/or providers that sell them services. In addition, health care administrators and insurers must provide clinicians with assistance to ensure that institutional changes promoting smoking cessation interventions are universally and

Table 5 Suggestions for the clinical use of nicotine gum

Parameter of clinical use	Suggestion
Patient selection Precautions	Appropriate as a primary pharmacotherapy for smoking cessation  Pregnancy: Pregnant smokers should first be encouraged to attempt cessation without pharmacologic treatment. Nicotine gum should be used during pregnancy only if the increased likelihood of smoking cessation, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking.  Cardiovascular diseases: Although not an independent risk factor for acute myocardial events, nicotine gum should be used only after consideration of risks and benefits among particular cardiovascular patient groups: those in the immediate (within four weeks) post-myocardial infarction period, those with serious arrhythmias, and those with serious or
	worsening angina pectoris.  Adverse effects: Common adverse effects of nicotine chewing gum include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient and can often be alleviated by correcting the patient's chewing
Dosage	Dosage: Nicotine gum is available in doses of 2 mg and 4 mg per presence for it, have failed with the 2-mg gum initially. The 4-mg gum should be prescribed to patients who express a preference for it, have failed with the 2-mg gum initially. The 4-mg gum should be prescribed for the but remain motivated to quit, and/or are highly dependent on nicotine. The gum is most commonly prescribed for the first few months of a quit attempt. Clinicians should tailor the duration of therapy to fit the needs of each patient. Patien using the 2-mg strength should use not more than 30 pieces per day, whereas those using the 4-mg strength should not
Prescribing instructions	exceed 20 pieces per day.  Abstinence from smoking: The instructions patient should refrain from smoking while using the gum.  Abstinence from smoking: The instructions patient should refrain from smoking while using the "parked" between cheek and Chewing technique: The gum should be chewed slowly until a "peppery" taste emerges, then "parked" between cheek and gum to facilitate nicotine absorption through the oral mucosa. Gum should be slowly and intermittently chewed and
	parked for about 30 minutes.  Absorption: Acidic beverages (e.g., coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating a drinking anything except water should be avoided for 15 minutes before and during chewing. Scheduling of dose: A common problem is that patients do not use enough gum to get the maximum benefit: they chew to few pieces per day and do not use the gum for a sufficient number of weeks. Instructions to chew the gum on a fixed schedule (at least one piece every 1-2 hours) for at least 1-3 months may be more beneficial than ad lib use.

# Table 6 Clinical guidelines for prescribing nicotine replacement products

Available research shows that nicotine replacement therapy generally increases rates of smoking cessation. Therefore, except in 1. Who should receive nicotine replacement therapy? special circumstances, the clinician should encourage the use of nicotine replacement with patients who smoke. Little research is available on the use of nicotine replacement with light smokers (i.e., those smoking ≤10-15 cigarettes/day). If nicotine replacement is to be used with light smokers, a lower starting dose of the nicotine patch or nicotine gum should be considered.

2. Should nicotine replacement therapy be tailored to the individual smoker?

Research does not support the tailoring of nicotine patch therapy (except with light smokers as noted above). Patients should be prescribed the patch dosages outlined in 1able 4.

Research supports tailoring nicotine gum treatment. Specifically, research suggests that 4-mg gum rather than 2-mg gum be used with patients who are highly dependent on nicotine (e.g., those smoking >20 cigarettes/day, those who smoke immediately used with patients who are highly dependent on nicotine (e.g., those smoking >20 cigarettes/day, those who smoke immediately used with patients who are highly dependent on nicotine (e.g., those smoking >20 cigarettes/day, those who smoke immediately used with patients who are highly dependent on nicotine (e.g., those smoking >20 cigarettes/day, those who smoke immediately used with patients who are highly dependent on nicotine (e.g., those smoking >20 cigarettes/day). upon awakening, and those who report histories of severe nicotine withdrawal symptoms). Clinicians may also recommend the higher gum dose if patients request it or have failed to quit using the 2-mg gum.

3. Should patients be encouraged to use the nicotine patch or nicotine gum?

While both pharmacotherapies are efficacious, panel opinion is that nicotine patch therapy is preferable for routine clinical use. This preference is based on the following comparisons with nicotine gum therapy:

Nicotine patch therapy is associated with fewer compliance problems that interfere with use.

Nicotine patch therapy requires less clinician time and effort to train patients in its effective use.

The following factors would support the use of nicotine gum:

Patient preference

Previous failure with the nicotine patch

Contraindications specific to nicotine patch use (e.g., severe skin reactions).

# Table 7 Findings relevant to the specialist's implementation of intensive cessation programs

- 1. There is a strong dose-response relation between counseling intensity and cessation success. In general, the more intense the cessation intervention, the greater the rate of smoking cessation. Treatments may be made more intense by increasing the length of individual treatment sessions or increasing the number of treatment sessions and number of weeks over which treatment is
- 2. Valid predictors of outcome are available. For instance, high levels of dependence, psychiatric comorbidity, and low levels of motivation to quit all predict greater likelihood of relapse. These measures might be used to adjust treatment intensity, to match patients with particular types of treatment, or for research purposes.
- 3. Many different types of cessation providers (e.g., physicians, nurses, dentists, psychologists, pharmacists) are effective in increasing rates of smoking cessation, and involving multiple types of cessation providers appears to enhance cessation rates.

4. Both individual and group counseling are effective smoking cessation formats.

- 5. Particular counseling contents are especially effective. Problem-solving/skill-training approaches and the provision of intratreatment support are associated with significant increases in cessation rates.
- 6. Pharmacotherapy in the form of nicotine patch or nicotine gum therapy consistently increases smoking cessation rates regardless of the level of adjuvant behavioral or psychosocial interventions. Therefore, its use should be encouraged.
- 7. Smoking cessation interventions are effective across diverse populations: across sex, racial, and ethnic groups, across age groups, and in pregnant women.

systematically implemented. Finally, performance indicators directed at both tobacco-use monitoring and treatment should be implemented to assess both health plan and provider performance.<sup>32</sup> Implementation of a number of institutional policies would facilitate these outcomes (Table 9):

- and monitor use of a Implement tobacco-user identification system in every medical setting.
- Provide education, resources, and feedback to promote provider intervention.
- Dedicate staff to provide smoking cessation treatment identified as effective in this document and assess the delivery of this treatment in staff performance evaluations.
- Promote hospital policies that support and provide smoking cessation services.
- Include smoking cessation treatment (both pharmacotherapy and counseling) identified as effective in this Guideline as paid

services for all subscribers of health insurance packages.

Reimburse fee-for-service clinicians for delivery of effective smoking cessation treatments and include these interventions among the defined duties of salaried clinicians.

### Guideline recommendations of general interest

1. PROMOTING THE MOTIVATION TO QUIT Despite receiving a clinician's advice to quit smoking, many patients are not willing to make a commitment to quit at the time of a health care visit. These patients may be uninformed, concerned about the effects of quitting, or demoralized due to previous failure. Such patients may respond to a motivational intervention. Motivational interventions that may help clinicians promote smoking cessation

Table 8 Recommendations regarding intensive smoking cessation programs

Assessment: Assessments should determine whether smokers are motivated to quit smoking via an intensive smoking cessation program. Other assessments can provide information useful in counseling (e.g., stress level, presence of comorbidity).

Program clinicians: Multiple types of clinicians should be used. One strategy would be to have a medical/health care clinician deliver messages about health risks and benefits and nonmedical clinicians deliver psychosocial or behavioral interventions. Program intensity: Because of evidence of a strong dose-response relation, the program should be at least 20-30 minutes in length, should include at least 4-7 sessions, and should last at least two weeks, preferably more than eight weeks.

Program format: Either individual or group counseling may be used. Use of adjuvant self-help material is optional. Follow-up assessment procedures should be used.

Counseling content: Counseling should involve either problem-solving or skill-training content or both as well as social support delivered during treatment sessions. In addition, the content should target motivation to quit and relapse prevention. Pharmacotherapy: Except in special circumstances, every smoker should be offered nicotine replacement therapy. The clinician should encourage the use of nicotine patch or nicotine gum therapy for smoking cessation (see Tables 4 and 5 for specific instructions and precautions).

Population: Intensive intervention programs may be used with all smokers willing to enter such programs

<sup>\*</sup>A session length of 20-30 minutes was recommended because most trials of effective smoking cessation counseling used sessions of at least this length.

### Table 9 Institutional policies\*

Action

Strategies for Implementation

1. Implement a tobacco-user identification system in every medical setting Implement an officewide system patient at every clinic visit, tobacco-use status is queried and documented.†

Office system change: Expanding the vital signs to that ensures that for every include

Responsible staff: Nurse, medical assistant, receptionist, or other individual already responsible for measuring the vital signs—no additional staff requirements. The staff must be instructed regarding the frequency and importance of this activity. Frequency of utilization: Every visit for every patient regardless of the reason that brought the individual to the clinic.† In other words, whenever health care staff collect the traditional vital signs data, they also query and document tobacco use.

System implementation steps: Preprint progress note paper or preprogram the computer record for every patient visit to include tobacco use along with the traditional vital signs. A vital sign stamp can also be effective (see Figure).

2. Provide education, resources, and feedback to promote provide Health care systems should ensure that clinicians have the knowledge and training to treat patients who smoke, that clinicians and patients have cessation resources, and that clinicians are given feedback about their cessation practices.

Educate: On a regular basis, offer lectures/seminars/in-service training with CME and er intervention other credit for smoking cessation treatment.

Provide resources: Have patient self-help materials and nicotine replacement starter kits readily available in every examination room.

Provide feedback: Draw on data from chart audits, electronic medical records, and computerized patient databases to evaluate the degree to which clinicians are identifying, documenting, and treating patients who smoke and provide feedback to clinicians about their level of intervention.

3. Dedicate staff to provide tobacco intervention treatment and a Clinical sites should communicate to staff the importance of intervening with smokers and should his or her responsibilities in the provision of designate one staff person (e.g., a nurse, medical assistant, or other clinician) to coordinate and provide tobacco dependence treatments.

ssess the delivery of this treatment in staff performance evaluations

Communicate to each staff member (e.g., nurses, medical assistants, and other clinicians) smoking-cessation services.

Designate a smoking cessation treatment coordinator for every clinical site. Delineate the responsibilities of the smoking cessation coordinator, including instructing patients on the effective use of cessation treatments (e.g., nicotine replacement therapy, telephone calls to and from prospective quitters, and scheduled follow-up visits, especially in the immediate postquit period).

4. Promote hospital policies that support and provide tobacco intervention services Provide smoking cessation inpatient consultation services to all smokers admitted to a hospital.

Implement a system to identify and document the tobacco-use status of all hospitalized

patients. Offer cessation treatment to all hospitalized patients who use tobacco.

Identify a clinician(s) to provide smoking cessation inpatient consultation services for every hospital.

Reimburse providers for smoking cessation inpatient consultation services. Expand hospital formularies to include effective smoking cessation pharmacotherapy such

as the nicotine patch and nicotine gum Ensure compliance with JCAHO regulations mandating that all sections of the hospital be

Educate all hospital staff regarding nicotine withdrawal, including effective treatments such as nicotine replacement therapy and counseling

5. Include tobacco intervention treatments (both pharmacotherapy and counseling) identified as effective in this guideline as paid services for all subscribers of health insurance packages

Provide all insurance subscribers coverage for effective tobacco intervention treatments, including pharmacotherapy (nicotine replacement therapy) and counseling.

Cover: Include effective smoking cessation treatments (both pharmacotherapy and counseling) as part of the basic benefits package for all individual, group, and HMO

insurance packages.

Evaluate: Include the provision of smoking cessation treatment as part of "report cards" for managed care organizations and other insurers (eg, HEDIS).

Educate: Inform subscribers of the availability of covered smoking cessation services and encourage patients to use these services.

6. Reimburse fee-for-service clinicians for provision of effective tobacco intervention treatments and include these interventions among the defined duties of salaried clinicians Reimburse fee-for-service clinicians for provision of effective tobacco

intervention treatments; include smoking cessation treatments in the defined duties of salaried clinicians.

Include smoking cessation treatment as a reimbursable activity for fee-for-service providers. Inform fee-for-service clinicians that they will be reimbursed for using effective tobacco intervention treatments with every patient who uses tobacco.

Include tobacco intervention in the job description and performance evaluation of salaried clinicians.

\*CME indicates continuing medical education; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; HMO, health maintenance organization; and HEDIS, Health Plan Employer Data and Information Set.

†Repeated assessment is not necessary in the case of the adult who has never smoked or not smoked for many years, and for whom this information is clearly documented in the medical record.

are characterized by the four R's: relevance, risks, rewards, and repetition (Table 10).

Panel recommendation: For patients not willing to initiate a quit attempt at the time of their health care visit, clinicians should engage in a brief intervention designed to promote motivation to quit (strength of evidence = C).

. RELAPSE PREVENTION

Because of the high rates of relapse after initial abstinence, clinicians must employ strategies to assist their patients in maintaining abstinence. While relapse prevention interventions may be used with any ex-smoker when judged appropriate by the clinician, it is vital that such interventions be delivered to any smoker who has stopped within the past three months. This is a period of high risk for relapse.33 34

Relapse prevention interventions can be delivered via either prearranged telephone calls or clinic visits, or anytime the clinician encounters an ex-smoker. It is vital that a systematic, institutionalized mechanism be in place to identify ex-smokers, because that is a necessary first step in delivering relapse prevention messages. Relapse prevention interventions can be divided into two categories:

#### Minimal practice

These relapse prevention interventions should be part of every primary care encounter with a patient who has recently quit (Table 11). Because most relapse occurs within the first three months after quitting, relapse prevention is especially appropriate during this period.

Table 10 Components of clinical interventions designed to enhance motivation to quit smoking: the four Rs

Relevance: Motivational information given to a patient will have the greatest impact if it is relevant to his or her concerns and disease status, family or social situation (e.g., having children in the home), age, sex, and other important characteristics (e.g.,

Risks: The clinician should ask the patient to identify the potential negative consequences of smoking. The clinician may suggest and highlight those that seem most relevant to the patient. The clinician should emphasize that smoking low-tar, low-nicotine cigarettes or using other forms of tobacco (e.g., smokeless tobacco, cigars, pipes) will not eliminate these risks. Examples of risk include

Acute risks: Shortness of breath, exacerbation of asthma, impotence, infertility, pregnancy-related risks, increased serum

Long-term risks: Heart attacks and strokes, lung and other cancers (larynx, oral cavity, pharynx, esophagus, pancreas, bladder,

cervix, leukemia), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema) Environmental risks: Increased risk of lung cancer in spouse and children, higher rates of smoking by children of smokers, and increased risk for sudden infant death syndrome, asthma, middle ear disease, and respiratory infections in children of smokers. Rewards: The clinician should ask the patient to identify the potential benefits of quitting smoking. The clinician may suggest and

highlight those that seem most relevant to the patient. Examples of rewards include

Improved health Better-tasting food Improved sense of smell Saving money Feeling better about oneself Better-smelling home, car, and breath Freedom from worrying about quitting Setting a good example for children Having healthy infants and children

Freedom from worrying about exposing others to smoke

Feeling better physically Freedom from addiction

Repetition: The motivational intervention should be repeated every time the patient visits the clinic setting.

#### Prescriptive interventions

relapse prevention These individualized components are based upon information obtained regarding problems the patient has encountered in maintaining abstinence. These more intensive relapse prevention interventions (Table 11) may be delivered via primary care or through a specialist or smoking cessation program.

Panel recommendation: When clinicians encounter a recent quitter, they should reinforce their patient's decision to quit, review the benefits of quitting, and assist the patient in resolving any residual problems arising from quitting (strength of evidence = C).

3. SMOKER'S SEX AND SMOKING CESSATION One frequent question regarding quitting smoking is whether men and women should receive different cessation interventions. The panel's review of the clinical trial literature revealed no consistent difference between men and women in cessation rates.35 Moreover, epidemiologic studies do not show a consistent difference between men and women in quit attempts or success rates.36 Few studies, however, have examined programs specifically

tailored to one sex. Panel recommendation: The same smoking cessation treatments are effective for both men and women. Therefore, the same interventions can be used with both sexes (strength of evidence = B).

4. RACIAL AND ETHNIC MINORITIES

Ethnic and racial minority groups in the United States (i.e., African Americans, Native Americans, Alaskan Natives, Asian Americans and Pacific Islanders, Hispanics) experience higher mortality in a number of disease categories than the white majority. For example, African Americans experience substantial excess mortality from cancer, cardiovascular disease, and infant death, all of which are directly affected by tobacco use.37 American Indians

and Alaskan Native subgroups have some of the highest documented rates of infant mortality due to sudden infant death syndrome.38 Therefore, there is a critical need to deliver effective smoking intervention to ethnic and racial minorities.

There are well-documented differences between racial and ethnic minorities and the white majority in smoking patterns and in smoking and quitting prevalence.39 40 In addition, smoking prevalence and patterns vary substantially among minority subgroups.38 Racial and ethnic minorities also differ from whites in terms of awareness of the health effects of smoking41 and a sense of fatalism that may affect disease prevention efforts. On the other hand, both nicotine addiction and desire to quit appear to be prevalent across all racial and ethnic groups. 39 40 42

Few studies have examined interventions specifically tailored to particular ethnic or racial groups, and there is no consistent evidence that tailored cessation programs result in higher quit rates among these groups. Moreover, smoking cessation interventions developed for the general population have been effective with racial and ethnic minority participants. Therefore, clinicians who see minority group patients should offer treatments identified as effective in this Guideline.

Because of the small amount of research on this topic, there is currently little support for the obligatory tailoring of cessation treatments for minority populations. Logically, however, it is clear that tailoring may sometimes be necessary for effective intervention. For instance, cessation counseling or self-help materials must be conveyed in a language that is understood by the smoker. Additionally, culturally appropriate models or examples may increase the smoker's acceptance of treatment. Therefore, tailoring for minority populations should be done when possible. Certainly, practices with multiethnic or multiracial

Components of minimal practice relapse prevention interventions

- Components of minimal practice relapse prevention interventions

  1. Every ex-smoker receiving relapse prevention intervention should receive congratulations, encouragement, and concern on the part of the clinician that the patient remain abstinent.
- 2. The clinician should encourage the patient's active discussion of the following topics. The clinician should ask the patient open-ended questions designed to initiate the patient's problem solving on these topics (e.g., "Do you think that stopping smoking will help you? How?"

A review of the benefits, including potential health benefits, the patient may derive from cessation A review of the patient's success in quitting (e.g., duration of abstinence, reduction in withdrawal) An inquiry about problems encountered in maintaining abstinence (e.g., depression, weight gain)

Anticipation of problems or threats to maintaining abstinence

During relapse prevention, an inquiry about problems encountered in maintaining abstinence might lead the clinician to make Components of prescriptive relapse prevention interventions recommendations or offer treatment designed to address specific problems reported by the patient. Specific problems likely to

1. Weight gain: The clinician might make dietary, exercise, or lifestyle recommendations or might refer the patient to a specialist or program. The patient can be reassured that some weight gain after quitting is common and that significant dietary restrictions

2. Negative mood or depression: If this is a serious problem, the clinician might prescribe appropriate medications or refer the

3. Prolonged withdrawal symptoms: If the patient reports prolonged craving or other withdrawal symptoms, the clinician might

4. Lack of support for cessation: The clinician might schedule follow-up telephone calls with the patient, help the patient identify sources of support within his or her environment, or refer the patient to an appropriate organization that offers cessation counseling or support.

populations should make culturally appropriate materials available whenever resources permit.

Panel recommendations: (1) Members of racial and ethnic minorities should be provided smoking cessation treatments shown to be effective in this Guideline (strength of evidence = B). (2) Whenever possible, smoking treatments should be modified or tailored to be appropriate for the ethnic or racial populations with whom they are used (strength of evidence =

5. PREGNANCY AND SMOKING CESSATION Smoking in pregnancy presents risks to both the woman and the fetus.43 Many women are motivated to quit during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the fact that cessation will be best for the fetus, with postpartum benefits for both mother and child. On the other hand, clinicians should be aware that substantial numbers of pregnant women may try to hide their smoking status.44

While quitting smoking prior to conception or early in the pregnancy is most beneficial, there are health benefits from cessation at any time. Therefore, a pregnant woman who still smokes should continue to be encouraged and helped to quit. Among women who stop smoking during pregnancy, there is a high rate of relapse in the postpartum period, 43 even among women who have maintained total abstinence from tobacco for 6 or more months during pregnancy. Postpartum relapse may decreased by continued emphasis on the

relationship between maternal smoking and poor health outcomes (sudden infant death syndrome, respiratory infections, asthma, and middle ear disease) in infants and children. Table 12 outlines some clinical factors that are important to address when counseling pregnant women about smoking.

No clinical trials have assessed the benefits and risks of nicotine replacement therapy as an aid to smoking cessation in pregnant women. In a review of this topic, Benowitz45 concluded that, for pregnant women, the benefits of nicotine replacement therapy outweigh the risks of both continued smoking and nicotine replacement itself. Benowitz limited this conclusion, however, to those pregnant women who cannot stop without replacement therapy and suggested that benefits would be greatest for heavy smokers.

To assess the effectiveness of smoking cessation during pregnancy, the panel used both a published meta-analysis<sup>46</sup> and a meta-analysis conducted by panel staff. These two data sources resulted in essentially the same finding-smoking cessation interventions during pregnancy are effective and should be used to benefit both the woman and the fetus.

Panel recommendations: (1) Pregnant smokers should be strongly encouraged to quit throughout their pregnancy. Because of the serious risks of smoking to the pregnant smoker and her fetus, pregnant smokers should be offered intensive counseling treatment (strength of evidence = A). (2) Nicotine

Table 12 Clinical issues when assisting a pregnant patient in smoking cessation

Table 12 Clinical issues when assisting a program p		
Clinical issues	Rationale	
	Early quitting provides the greatest benefit to the	
Urge the patient to quit early in pregnancy if possible.	Commo	
Urge the patient to quit anytime during pregnancy.	The fetus benefits even when the woman quits later in pregnancy.  Both woman and fetus will benefit immediately.	
Stress the benefits of quitting early. Provide pregnancy-related motivational messages. Be alert to the patient's minimizing or denying tobacco use.	These are associated with higher quit rates.  Minimizing or denying smoking is common among program women who smoke.	
Assess the patient for relapse and use relapse prevention.	Postpartum relapse rates are high even if a woman maintains abstinence throughout pregnancy. Relapse prevention may start during pregnancy (see Table 11).	

6. SMOKING CESSATION AMONG HOSPITALIZED PATIENTS

Hospitalization can be an ideal opportunity for a patient to stop smoking, and smoking cessation may promote the patient's medical recovery. Among cardiac patients, second heart attacks are more common among those who continue to smoke.<sup>47</sup> Patients with lung, head, or neck cancer who are successfully treated, but continue to smoke, are at elevated risk for a second cancer.<sup>48</sup> Smoking negatively affects bone and wound healing.<sup>49</sup>

Every hospital in the United States must now be smoke free if it is to be accredited by the Joint Commission on Accreditation of Healthcare Organizations. As a result, hospitalized patients may have two reasons to be particularly motivated to make a quit attempt. First, the illness resulting in hospitalization may have been caused or exacerbated by smoking, highlighting the patient's personal vulnerability to the health risks of smoking. Second, motivation may be enhanced during hospitalization because the smoker is temporarily housed in a smoke-free environment. For these reasons, clinicians should use hospitalization as an opportunity to promote smoking cessation.50 51

Specifically, clinicians and hospital administrators should collaborate to ensure that systems are in place that identify the smoking status of all patients admitted to a hospital and that provide at least a brief clinical intervention to every hospitalized patient who smokes.

Finally, smokers may experience nicotine withdrawal symptoms during a hospitalization. Clinicians should consider providing temporary nicotine replacement therapy during a hospitalization to reduce such symptoms and should encourage the continued use of this therapy for patients desiring to prolong their abstinence.

Panel recommendation: For every hospitalized patient, the following steps should be taken: (1) Ask each patient on admission if he or she smokes and document the patient's smoking status; (2) for current smokers, list smoking status on the admission problem list and as a discharge diagnosis; (3) assist all smokers with quitting during the hospitalization, using nicotine replacement therapy if appropriate; and (4) provide advice and assistance on how to remain abstinent after discharge (strength of evidence = C).

7. WEIGHT GAIN AFTER SMOKING CESSATION Anxiety about weight gain is an important impediment to smoking cessation. Many smokers, especially women, are very concerned about their weight and fear that quitting will produce unwanted weight gain. Many also believe that there is little they can do to prevent postcessation weight gain except to return to smoking. These beliefs are especially difficult

to address clinically because they have some basis in fact. Research regarding weight gain and smoking cessation has identified a number of key facts:

- 1. The majority of smokers who quit smoking gain weight. Most will gain less than 4.5 kg (10 lb), but there is a broad range of weight gain, with as many as 10% of quitters gaining as much as 13.5 kg (30 lb).<sup>52</sup>
- 2. Women tend to gain slightly more weight than men, and for both sexes, African Americans, people under the age of 55 years, and heavy smokers (those smoking more than 25 cigarettes per day) are at elevated risk for major weight gain. 52 53
- 3. For many smokers, especially women, concerns about weight or fears about weight gain are motivators to start smoking or continue smoking. 54-56
- 4. The weight gain that follows smoking cessation is a negligible health threat compared with the risks of continued smoking.<sup>1 52</sup>
- 5. There are no experimentally validated strategies or treatments that are effective in preventing the postcessation weight gain. In fact, some evidence suggests that attempts to prevent weight gain (e.g., simultaneous dieting and quitting) may undermine the attempt to quit smoking. 57-59
- 6. Nicotine replacement—in particular, nicotine gum—appears to be effective in delaying postcessation weight gain. Moreover, there appears to be a dose-response relation between gum use and weight suppression (i.e., the more a patient uses nicotine gum, the less weight he or she gains). However, once nicotine gum use ceases, the quitting smoker gains an amount of weight that is about the same as if she or he had never used gum. <sup>53 60 61</sup>
- 7. Postcessation weight gain appears to be due to both increased intake (e.g., eating, alcohol consumption) and metabolic adjustments. The involvement of metabolic mechanisms suggests that even if quitting smokers do not increase their energy intake, they will still gain some weight. 62 63
- 8. Once a quitting smoker relapses and begins smoking at precessation levels, he or she will likely lose some or all of the weight gained during the quit attempt. 64 65

How should the clinician deal with concerns about weight gain? First, the clinician should neither deny the likelihood of weight gain nor minimize its significance to the patient. Rather, the clinician should warn the patient about the likelihood of weight gain and prepare the patient for its occurrence. However, the clinician should counter exaggerated fears about weight gain, given the relatively moderate weight gain that typically occurs. Certain types of information may help prepare the patient for postcessation weight gain (Table 13).

Second, before and during the quit attempt the clinician should stress that quitting smoking should be the patient's primary, immediate priority, and that the patient will be most successful in the long run if he or she tackles only one problem at a time (Table 13).

- Table 13 Clinician statements that may help a patient prepare for, and cope with, weight gain after smoking cessation
- 1. "The great majority of smokers gain weight once they quit smoking. However, even without special attempts at dieting or rice great majority of smokers gain weight once they quit sin exercise, weight gain is usually limited to less than 10 pounds.
- There is evidence that smokers will gain weight once they quit smoking even if they do not eat more. Weight gain appears to
- 3. "The amount of weight that you will likely gain from quitting will be a minor health risk compared with the risks of continued
- 4. "Try to put your concerns about weight on the back burner. You are most likely to be successful if you first try to quit smoking, and then later take steps to reduce your weight. Tackle one problem at a time! After you have quit smoking successfully, we can talk about how to reduce your weight."
- 5. "I know weight is important to you, and that you don't want to gain a lot of weight. However, temporarily—just until you are confident that you have quit smoking for good—let's focus on strategies to get you healthy rather than on weight. Think about eating plenty of fruits and vegetables, getting regular exercise, getting enough sleep, and not eating a lot of fats. Right now, this is probably the best thing that you can do for both your weight and your smoking. Eat plenty of healthy foods—don't starve
- yourself!"

  "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living "While you may gain some weight after quitting smoking, compare the importance of healthy living "While you may gain some weight after quitting smoking, compare the importance of the property of you will gain, your better appearance (less wrinkled skin, whiter teeth), fresher breath, and good feelings about quitting.

Third, during the quit attempt, the clinician should offer to help the patient address weight gain (either personally or via referral) once the patient has successfully quit smoking. Specifically, the clinician should recommend that intensive weight control strategies be avoided until the patient is no longer experiencing withdrawal symptoms and is confident that he or she will not return to smoking. However, the patient should be encouraged throughout the quit attempt to maintain or adopt a healthy lifestyle that includes moderate exercise, eating plenty of fruits and vegetables, and limiting alcohol consumption.

Panel recommendations: (1) The clinician should inform smokers that they are likely to gain weight when they stop smoking. The clinician should recommend that smokers not take strong measures (e.g., strict dieting) to counteract weight gain during a quit attempt. Moreover, ex-smokers should wait until they are confident that they will not return to smoking before trying to reduce their weight (strength of evidence = C). (2) For smokers who are greatly concerned about weight gain, the clinician may prescribe or recommend nicotine gum, which has been shown to delay weight gain after quitting (strength of evidence = A).

## 8. SMOKELESS TOBACCO USE

Like cigarette smoking, the use of smokeless tobacco, such as chewing tobacco and snuff, has serious health consequences. Consumption of smokeless tobacco products has increased in recent years, 66 67 especially among young males. Clinicians should offer quitting advice and assistance to their patients who use smokeless tobacco.

Despite a need for clinical guidance regarding interventions with patients who use smokeless tobacco, currently there is little research information to guide such treatment. A small number of studies have evaluated both multicomponent and brief counseling interventions for smokeless tobacco use cessation. The results of these evaluations suggest that the same cessation interventions that are effective with smokers are effective with smokeless tobacco users. Currently, there is little evidence on the effectiveness of pharmacologic treatments for smokeless tobacco use. This is an important area for further research.

Smokeless recommendations: (1) Panel tobacco (chewing tobacco and snuff) users

should be identified and strongly encouraged to quit (strength of evidence = C). (2) Smokeless tobacco users should be treated with the same counselling cessation interventions that are recommended for smokers (strength of evidence = B).

#### Conclusions

In summary, the Guideline panel's major recommendations are as follows:

- 1. Clinicians should assess the smoking status of every patient and should offer each patient an effective smoking cessation treatment.
- 2. Long-duration, intense treatments are more effective than brief treatments; however, even quite brief treatments, such as a physician's advice to stop smoking, can be efficacious in increasing long-term smoking cessation.
- 3. Nicotine replacement therapy (nicotine patches or nicotine gum), cliniciandelivered social support, and skill training are effective components of smoking cessation treatment.
- 4. Effective reduction of tobacco use requires that health care systems make institutional changes that result in the systematic identification of, and intervention with, all tobacco users, and that reimbursement be provided for clinicians' delivery of effective treatments.
- 5. Clinicians should (a) motivate smokers to make a quit attempt; (b) deliver relapse prevention interventions to all smokers who have recently quit; (c) encourage pregnant smokers to receive intensive smoking cessation counseling treatment and possibly nicotine replacement therapy; (d) assist all hospitalized smokers to remain abstinent from tobacco during and after the period of their hospitalization; (e) warn smokers about the weight gain they may experience after quitting and recommend nicotine gum as a method to delay the weight gain; (f) offer smokeless tobacco users the same smoking cessation counseling treatments that are used with smokers; and (g) offer both women and men as well as members of minority groups the cessation treatments listed as effective in this Guideline.

The Smoking Cessation Clinical Practice Guideline Panel and Staff include the following: Michael C. Fiore, MD, MPH, Center for Tobacco Research and Intervention, University of Wisconsin Medical School, Madison, chair; David W. Wetter, PhD, University of Texas M.D. Anderson Cancer Center,

Houston; William C. Bailey, MD, University of Alabama at Birmingham; Glen Bennett, MPH, National Heart, Lung, and Blood Institute. National Institutes of Health, Bethesda, Md; Stuart J. Cohen. EdD, Bowman Gray School of Medicine, Winston-Salem, NC; Sally Faith Dorfman, MD, MSHSA, Cornwall, NY; Michael G. Goldstein, MD, The Miriam Hospital, Brown University School of Medicine, Providence, RI; Ellen R. Gritz, PhD, University of Texas M. D. Anderson Cancer Center, Houston; Victor Hasselblad, PhD, Duke University, Durham, NC; Jack E. Henningfield, PhD, National Institute on Drug Abuse, National Institutes of Health, Baltimore, Md; Richard B. Heyman, MD, American Academy of Pediatrics, Cincinnati, Ohio; John Holbrook, MD, University of Utah School of Medicine, Salt Lake City; Corinne Husten, MD, MPH, Office on Smoking and Health, Centers for Diseas Control and Prevention, Atlanta, Ga; Carlos Roberto Jaen, MD, PhD, Center for Urban Research in Primary Care, State MPH, Office on Smoking and Health, Centers for Disease Control and Prevention, Atlanta, Ga; Carlos Roberto Jaen, MD, PhD. Center for Urban Research in Primary Care, State University of New York at Buffalo; Connie Kohler, DrPH, University of Alabama at Birmingham; Thomas E. Kottke, MD, MSPH, Mayo Clinic and Foundation, Rochester, Minn; Harry A. Lando, PhD, University of Minnesota, Minneapolis; Marc Manley, MD, MPH, National Cancer Institute, National Institutes of Health, Rockville, Md; Robert Mecklenburg, DDS, MPH, National Cancer Institute, Potomac, Md; Cathy Melvin, PhD, MPH, Centers for Disease Control and Prevention, Atlanta, Ga; Patricia Dolan Mullen, DrPH, Center for Health Promotion Research and Development, University of Texas, Houston; Louise M. Nett, RN, RRT, PSL/Health ONE, Center for Health Science Studies, Denver, Colo; Thomas M. Piasecki, MS, Center for Tobacco Research and Intervention, University of Wisconsin Medical School, Madison; Lawrence Robinson, MD, MPH, Philadelphia (Pa) Department of Public Health; Debra Rothstein, PhD, Office on Disease Prevention and Health Promotion, Washington, DC; David L. Schriger, MD, MPH, UCLA School of Medicine, Los Angeles, Calif; Maxine L. Stitzer, PhD, Johns Hopkins/Bayview Medical Center, Baltimore, Md; Sylvie Stachenko, MD, MSC, FCFP, Health Canada, Ottawa, Ontario; Anthony Tommasello, MS, University of Maryland at Baltimore School of Pharmacy; Louise Villejo, MPH, CHES, University of Texas M. D. Anderson Cancer Center, Houston; Mary Ellen Wewers, PhD, RN, College of Nursing, Ohio State University, Columbus; and Timothy B. Baker, PhD, Center for Tobacco Research and Intervention, University of Wisconsin Medical School, Madison.

Drs Fiore and Baker have worked on clinical research studies

Madison.

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# Open discussion: the AHCPR smoking cessation guideline

HARRY LANDO: Why another set of smoking cessation guidelines?

MICHAEL C FIORE: If one message were to come out of the guideline development process and the panel's efforts, it would be that there needs to be a spectrum of smoking cessation services. On one side are universal identification and documentation of smoking status and universal provision of at least a brief intervention, regardless of what brought a patient to a healthcare setting. But understanding that a brief intervention may not be enough for many individuals, we also need to provide more intensive intervention. I know the guideline panel looks forward to working particularly with managed-care organisations to identify that spectrum of care that can be provided for patients addicted to tobacco. To reassure them that they are not signing on to some extraordinarily high-cost intervention, we could provide two bits of support. One is the costeffectiveness data that I shared with you, and the second is that most patients self-select to non-intensive intervention, so it is going to be a subsample of patients addicted to tobacco.

PARTICIPANT: Where does nicotine nasal spray fit into the scheme of things?

MICHAEL C FIORE: Nicotine nasal spray and the inhaler, for that matter, were just beginning to have published data available at the time the panel was deliberating. We had to set a cut-off for our literature review, and we did that at the end of 1994. The guideline addresses those two pharmacotherapies, but concludes that there is insufficient data to

make a recommendation on their use. It would make sense that those agents, like other nicotine replacement agents that were tried, appear to be efficacious. But I think the critical question that the guideline didn't address is: are they first-line agents or are they held in reserve?

PARTICIPANT: Would you comment other new products, such as patches for nicotine receptor site blockade?

MICHAEL C FIORE: I am going to defer to the findings of the panel, which are that there were not sufficient data to address or to recommend such agents. The panel relied on published literature as the basis for making major recommendations. What it concluded is that there is an overwhelming body of evidence to recommend the nicotine patch and nicotine gum, but not to recommend any other pharmacotherapy at this time.

MITCHELL NIDES: Will there be a presentation kit to use with physicians and health maintenance organisations to educate them about the guidelines?

MICHAEL C FIORE: The agency is committed to producing a series of slides, some of which have already been prepared, and they will make certain that those are available for people who want to use them. The goal of all of this is to get the word out as broadly as possi-

PARTICIPANT: You mentioned a couple of times a dose-response and session-response ratio. One of my concerns is that we have a self-selection among patients-that once people relapse, they will stop taking the medication or they will stop going to sessions, so that they were arbitrarily concluding that more treatment works better as opposed to less treatment.

MICHAEL C FIORE: I don't profess to be a meta-analytical expert, but I am going to comment on it to the extent that I can. The studies included both patients that selfselected, as well as studies that included all-comers to clinic settings. I believe that the meta-analyses which addressed, in this instance, the intensity of counselling-because counselling that had the it was the dose-response relationship-included both self-selected, as well as clinic-wide populations, and had at least two intensities. We were able to conclusively because this meta-analysis had more than 50 studies involved. We have confidence in all the recommendations.

STEVEN MONDRE: Personally, I have for the past few years been using nicotine floss to help my patients stop smoking. It is nice outreach to tell dentists to encourage their patients to stop smoking, but in reality it is not going to work unless there is a real mechanism involved.

MICHAEL C FIORE: One of the key clinician groups identified are dentists, and we look forward to working with them in ensuring that they take their unique access to people who use tobacco. Our panel did not have any data to address the issue of nicotine floss.

**PARTICIPANT:** Many managed-care administrators are trying to understand what guidelines they ought to be using in their disease management efforts. Very little is being said about smoking cessation even within the cardiovascular arenas. Have you addressed them?

MICHAEL C FIORE: Well, three key audiences identified were healthcare administrators, insurers, and purchasers. The panel felt

strongly that unless this group was brought on board, this was not going to work. Dr Orleans chaired the work of [the] Robert Wood Johnson [Foundation] in ensuring that some of the report cards for these groups, like HEDIS [the Health Employer Data and Information Set], will include something about tobacco. One of the goals of the Robert Wood Johnson Foundation, as well as the Agency for Health Care Policy and Research, is to work with these groups to ensure it happens, but it is going to be a challenge.

PARTICIPANT: What response do you have for comments that I have heard from the insurance industry and managed care: "Why should we reimburse for smoking cessation? The patients change programmes so quickly that we are not going to see the benefits of it. Why should we pay for it?"

MICHAEL C FIORE: One clear reason is we are in the business of health promotion and disease prevention, and I think that that should probably be enough in and of itself, but obviously it is not. The cost-effectiveness argument (which should be available in a report that the agency will be releasing in the next couple of months) will go a long way in addressing the cost issues, as well as the period of time that it takes to get a payback. The other notion is, if this is universally implemented, everyone benefits from those costs.

**PARTICIPANT:** What do you tell physicians so that they can get reimbursed for their cessation efforts?

MICHAEL C FIORE: There is a psychiatric coding, tobacco addiction, that currently exists. Many clinicians treat smoking cessation as part of treating underlying diseases, whether it is an acute bronchitis or a chronic condition, but I think we need to go beyond the old practice of just trying to wiggle our way around the billing issues, and encourage clinicians to cover those cessation services. We need to change the coverage system.